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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,777	06/14/2001	James E. Audia	002010-685	1280

7590 12/20/2001  
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EXAMINER

KIFLE, BRUCK

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/20/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/882,777

Applicant(s)  
Audia et al.

Examiner  
Bruck Kifle

Art Unit  
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 14, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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The search of the elected compound revealed that the elected compound is disclosed in:

- 1) WO 99/67220 (equivalent of pending US application 09/337,484);
- 2) WO 99/67219 and WO 99/66934 (equivalent of pending US application 09/338,180);
- 3) WO 99/32453 (equivalent of pending US applications 08/996,422 and instant 09/337,408).

Applicants are required to maintain a clear line of demarcation between these applications. See MPEP § 822.

### ***Improper Markush Rejection***

Claims 1-62 are rejected under a judicially created doctrine as being drawn to an improper Markush group, that is, the claims lack unity of invention. The variables  $R^1$ ,  $n$  and  $W$  are defined in such a way that they keep changing the core of the compound that determines the classification. By changing these values, several patentably distinct and independent compounds are claimed. In order to have unity of invention the compounds must have “a community of chemical or physical characteristics” which justify their inclusion in a common group, and that such inclusion is not repugnant to principles of scientific classification” In re JONES (CCPA) 74 USPQ 149 (see footnote 2). The structural formula (I) does not have a significant structural feature that is shared by all of its alternatives which is inventive. The structure has only the -NH- group as common. This feature is not inventive. Compounds embraced by formula (I) are so diverse in nature that a prior art anticipating a claim with respect to one member under 35 USC 102 would not render obvious the same claim under 35 USC 103. This is evidentiary of patentably distinct and independent inventions.

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The search has been expanded to embrace compounds wherein rings A and B are benzene rings and ring C does not contain any additional heteroatoms other than the nitrogen of the caprolactam. Limiting the claims to the genus searched would overcome this rejection.

***Claim Rejections - 35 USC § 112***

Claims 1-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms substituted alkyl, substituted alkenyl, substituted alkynyl, substituted cycloalkenyl are present in the claims. These terms are indefinite because one cannot tell which substituents are intended and which ones are not. Also, the terms heteroaryl and heterocyclic are indefinite because one cannot say which heteroatoms are present, how many of each are present, what size ring is intended and how many rings are present. A clarification is required.

Claims 1-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rings embraced at A, B and C are not adequately enabled as they read on rings and ring systems having diverse and multiple heteroatoms as ring members in any array with

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various fused rings for which there is no sufficient enabling disclosure by way of working examples or reasonable disclosure of starting material sources. In re Howarth, 210 USPQ 689; Ex parte Moersch 104 USPQ 122. Compounds as diverse as those embraced by the scope of the claims would not all be expected to share the same profile of activity nor are they shown to be active as a class. See In re Fisher 166 USPQ 18; In re Surrey, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

Rings A and B as benzene and ring C as an alkylene to complete the ring are enabled by the specification.


***Allowable Subject Matter***

The subject matter indicated as being searched above (compounds wherein  $n=1$  and W is the fused caprolactams, wherein rings A and B are benzene rings and ring C does not contain any additional heteroatoms other than the nitrogen of the caprolactam), is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

December 18, 2001

  
**Bruck Kifle**  
**Primary Examiner**  
**Art Unit 1624**